

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE: Application of Jodi Marie MAGLICH et al.

Serial No.: To be assigned

Art Unit:

Filing Date: Concurrently herewith

Examiner:

For: *Compositions and Methods for
Regulating Thyroid Metabolism and
Cholesterol and Lipid Metabolism
via the Nuclear Receptor CAR*

**Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450**

INFORMATION DISCLOSURE STATEMENT

Applicants request that the references identified on Form PTO-1449 appended hereto be considered by the Examiner and officially made of record in accordance with the provisions of 37 CFR 1.97

- ☒ Copies of the references listed on the attached form PTO-1449 as item nos. 1, 2 and 7-29 are enclosed
- ☐ Copies of the references were submitted in parent application Serial No. _____ (37 CFR 1.98(d))
- ☒ A copy of the International Search Report which issued on International Application No. PCT/US03/06089 is submitted herewith. All of the publications cited in the International Search Report are listed on the attached form PTO-1449 as item nos. 3-6 and Applicants understand that copies have been supplied to the U.S. Patent Office by the International Bureau.

- A. ☒ The Information Disclosure Statement submitted herewith is being filed within three months of the filing date of the above application or date of entry into the national stage of an international application or before the mailing date of a first Office action on the merits, whichever event occurs last. 37 CFR 1.97(b).

OR

- ☐ **The Information Disclosure Statement submitted herewith is being filed before the mailing of a first office action after the filing of a Request For Continued Examination under 37 C.F.R. 1.114 (37 C.F.R. 1.97(b)(4)).**

- B. ☐ The Information Disclosure Statement transmitted herewith is being filed **after** three months of the filing date of the above application or the date of entry into the national stage as set forth in § 1.491 of an international application or after the mailing date of the first Office Action on the merits, whichever event occurred last, but **before** the mailing date of either:

- (1) a final action under § 1.113 or
 - (2) a notice of allowance under § 1.311,
- whichever occurs first.

- ☐ Applicant hereby certifies that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this statement.

- ☐ Applicant elects the option to pay the fee set forth in 37 CFR 1.17(p) for submission of an Information Disclosure Statement under § 1.97(c) (\$180.00).

- C. ☐ The Information Disclosure Statement transmitted herewith is being filed **after** a final action under § 1.113, or a notice of allowance under § 1.311, whichever occurs first, but before the payment of the issue fee. Also enclosed is a copy of the International Search Report which Issued on International Publication No.

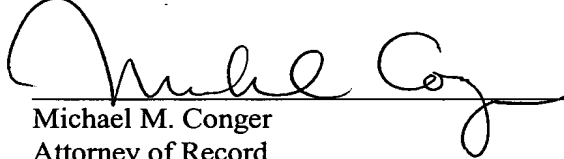
In accordance with the requirements of 37 CFR 1.97(d):

- ☐ Applicant hereby certifies that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this statement. **[or]**
- ☐ Applicant hereby certifies that no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to my knowledge after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of this statement; and
- ☐ The petition fee set forth in § 1.17(i)(1) (\$180.00) is submitted herewith.

☒ Please charge any required fees to Deposit Account No.07-1392.

☐ A duplicate copy of this paper is attached.

Respectfully Submitted,



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FORM PTO-1449 INFORMATION DISCLOSURE STATEMENT				ATTORNEY DOCKET NO. PU4591USw		SERIAL NO. 06647 <small>To be assigned</small>			
				APPLICANT Jodi Marie MAGLICH et al.					
				FILING DATE Concurrently herewith				GROUP	
U.S. PATENT DOCUMENTS									
Examiner Initials		Patent Number	Issue Date	Name	Class	Subclass	Filing Date If Appropriate		
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FOREIGN PATENT DOCUMENTS									
		Document Number	Publication Date	Country	Class	Subclass	Translation Yes No		
	1.	WO 01/51045	07/19/2001	WIPO					
	2.	WO 02/25134	03/28/2002	WIPO			X (Abstract)		
Continue on page _____									
OTHER DOCUMENTS (Including Author, Title, Journal-Date, Page Number, Etc.)									
	3.	Choi et al., "Differential transactivation by two isoforms of the orphan nuclear hormone receptor CAR," <i>Journal Biological Chemistry</i> 272(38) :23565-23571 (Sep. 1997).							
	4.	Moore et al., "Orphan nuclear receptors constitutive androstane receptor and pregnane X receptor share xenobiotic steroid ligands," <i>Journal Biological Chemistry</i> 275(20) :15122-15127 (May 2000).							
	5.	Sueyoshi et al., "The repressed nuclear receptor CAR responds to Phenobarbital in activating the human CYP2B6 gene," <i>Journal Biological Chemistry</i> 374(10) :6043-6046 (Mar. 1999).							
	6.	Wei et al., "The nuclear receptor CAR mediates specific xenobiotic induction of drug metabolism," <i>Nature</i> 407 :920-923 (Oct. 2000).							
	7.	Barter et al., "UDP-glucuronosyltransferase inducers reduce thyroid hormone levels in rats by an extrathyroidal mechanism," <i>Toxicol. Appl. Pharmacol.</i> 113 :36-42 (1992).							
	8.	Berti et al., "Thyroid hormone increases plasma cholesteryl ester transfer protein activity and plasma high-density lipoprotein removal rate in transgenic mice," <i>Metabolism</i> 50(5) :530-536 (May 2001).							
	9.	Burchell et al., "UDP Glucuronosyltransferases," <i>Pharmacol. Ther.</i> 43(2) :261-289 (1989).							
	10.	Diwan et al., "Enhancement of thyroid and hepatocarcinogenesis by 1,4-bis[2-(3,5-dichloropyridyloxy)]benzene in rats at doses that cause maximal induction of CYP2B," <i>Carcinogenesis</i> 17(1) :37-43 (Jan. 1996).							
	11.	Feng et al., "Thyroid hormone regulation of hepatic genes <i>in vivo</i> detected by complementary DNA microarray," <i>Mol. Endocrinol.</i> 14(7) :947-955 (Jul. 2000).							
	12.	Fields et al., "A novel genetic system to detect protein-protein interactions," <i>Nature</i> 340(6230) :245-246 (Jul. 1989).							
	13.	Honkakoski et al., "The nuclear orphan receptor CAR-retinoid X receptor heterodimer activates the Phenobarbital-responsive enhancer module of the CYP2B gene," <i>Mol. Cell. Biol.</i> 18(10) :5652-5658 (Oct. 1998).							
	14.	Hulsmann et al., "Effect of hypothyroidism, diabetes and polyunsaturated fatty acids on heparin-releasable rat liver lipase," <i>Biochem. Biophys. Res. Commun.</i> 79(3) :784-788 (1977).							
	15.	Iossa et al., "Fat balance and serum leptin concentrations in normal, hypothyroid, and hyperthyroid rats," <i>International Journal of Obesity</i> . 25(3) :417-425 (Feb. 2001).							
	16.	Keppler et al., "Hepatic secretion of conjugated drugs and endogenous substances," <i>Seminars in Liver Disease</i> . 20(3) :265-272 (2000).							
Continue on page <u>2</u>									
EXAMINER						DATE CONSIDERED			
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		Document Number	Publication Date	Country	Class	Subclass	Translation Yes No
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	17.	Kolaja et al., "Dose-response examination of UDP-glucuronosyltransferase inducers and their ability to increase both TGF- β expression and thyroid follicular cell apoptosis," <i>Toxicol. Sci.</i> 46(1) :31-37 (Nov. 1998).					
	18.	Lavery et al., "Circadian expression of the steroid 15 α -hydroxylase (<i>Cyp2a5</i>) and coumarin 7-hydroxylase (<i>Cyp2a5</i>) genes in mouse liver is regulated by the PAR leucine zipper transcription factor DBP," <i>Mol. Cell Biol.</i> 19(10) :6488-6499 (Oct. 1999).					
	19.	Nichols et al., "Development of a scintillation proximity assay for peroxisome proliferators-activated receptor γ ligand binding domain," <i>Anal. Biochem.</i> 257(2) :112-119 (Mar. 1998).					
	20.	Parks, "Bile acids: natural ligands for an orphan nuclear receptor," <i>Science</i> 284(5418) :1365-1368 (May 1999).					
	21.	Ridgway et al., "Lipoprotein lipase-mediated sequestration of long-chain polyunsaturated triacylglycerols in serum LDL from normal and hypothyroid rats," <i>Biochim. Biophys. Acta</i> 796(1) :64-71 (Oct. 1984).					
	22.	Ridgway et al., "Serum activity and hepatic secretion of lecithin: cholesterol acyltransferase in experimental hypothyroidism and hypercholesterolemia," <i>J. Lipid Res.</i> 26(11) :1300-1313 (Nov. 1985).					
	23.	Scarabottolo et al., "Experimental hypothyroidism modulates the expression of the low density lipoprotein receptor by the liver," <i>Atherosclerosis</i> 59(3) :329-333 (1986).					
	24.	Spiegelman et al., "Obesity and the regulation of energy balance," <i>Cell</i> 104(4) :531-543 (Feb. 2001).					
	25.	Sugatani et al., "The Phenobarbital response enhancer module in the human bilirubin UDP-glucuronosyltransferase <i>UGT1A1</i> gene and regulation by the nuclear receptor CAR," <i>Hepatology</i> 33(5) :1232-1238 (2001)					
	26.	Valdemarsson et al., "Relations between thyroid function, hepatic and lipoprotein lipase activities, and plasma lipoprotein concentrations," <i>Acta Endocrinol.</i> 104(1) :50-56 (1983)					
	27.	Xie et al., "Reciprocal activation of Xenobiotic response genes by nuclear receptors SXR/PXR and CAR," <i>Genes Dev.</i> 14(23) :3014-3023 (Dec. 2000).					
	28.	Yen, "Physiological and molecular basis of thyroid hormone action," <i>P.M. Physiol. Rev.</i> 81(3) :1097-1142 (Jul. 2001).					
	29.	Zelko et al., "Phenobarbital-elicited activation of nuclear receptor CAR in induction of cytochrome P450 genes," <i>Biochem. Biophys. Res. Comm.</i> 277(1) :1-6 (Oct. 2000).					
Continue on page _____							
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